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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|-----------------------------|
| 10/532,583 | 05/17/2005 | Gunter Langen | B1180/20037 | 4302 |
| 3000 7590 11/05/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212 | | | EXAMINER MOORE, MARGARET G | |
| | | | ART UNIT 1796 | PAPER NUMBER |
| | | | NOTIFICATION DATE 11/05/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/532,583 | Applicant(s) LANGEN ET AL. | |
| | Examiner Margaret G. Moore | Art Unit 1796 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 to 22, 24 to 30 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 16 to 18, 24 to 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 20, 22 and 33 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1796

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/28/07 has been entered.

2. The Examiner notes that claims 16 to 18 and 24 to 30 remain withdrawn from consideration as being drawn to non-elected inventions. This is consistent with that noted in the office action dated 12/12/06.

3. In view of applicants' amendment, the Examiner has withdrawn the previous grounds of rejection. The following new ground of rejection is made.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 19, 20, 22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. '802 in view of Ahola et al. '339.

Ahola et al. '802 teach multilayered material that is derived from a silica xerogel. See for instance column 3, lines 5 and on. Particularly note column 3, line 53, which teaches that the material body can be a woven or non-woven fabric. Such a fabric will meet the required wound dressing (as such a fabric meets the claimed flat textile form in claim 22). Column 5, lines 35 to 38, specifically teaches what can be considered a wound dressing.

Column 6 prepares a silica sol. Such a sol is a xerogel, as is apparent from the fact that this samples are dried¹. The silica sol in '802 includes a bioactive agent such as heparin for delivery. The silica sol in Ahola et al. '902 differs from that claimed in that it does not contain a hydrophobic organic silicon compound.

Ahola et al. '339 teaches that the addition of an organommodified alkoxysilane in a xerogel allows the skilled artisan to alter the controlled release of therapeutic agents therein. See for instance column 1, line 55 through column 2, line 24, and column 8, lines 38 and on. Specifically note that the presence of organommodified alkoxysilanes results in more brittle materials with increased drug release rate. The alkoxysilanes meet the organic silicon compound of claim 20.

Thus one having ordinary skill in the art would have found the inclusion of an alkyl alkoxysilane in the xerogel formation of Ahola et al. '802 to have been obvious, in an effort to optimize and/or adjust the release rate of the bioactive material therein. At the least one of ordinary skill in the art could have substituted the known silica gel in '802 with the silica gel in '339, both of which are known to be used in an equivalent manner, with an expectation of predictable results.

With this in mind, the Examiner also notes that neither reference discloses a coating weight for the silica gel. Ahola et al. '802 teach on column 4, lines 58 and 59, that the thickness of the layers can be widely varied depending on specific needs. The thickness of the layers corresponds to the weight of the layer. Since the skilled artisan has motivation to adjust the thickness according to need, this corresponds to motivation to adjust the amount, or weight, of coating on the body. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (i.e. does not require undue experimentation). In this manner the claimed weight requirement would have been obvious over the prior art teachings.

For claim 33, the Examiner notes that the language "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not

¹ Ahola et al. '339 defines xerogel as a dried gel (column 1, line 19).

materially affect the basic and novel characteristic(s) of the claimed invention. It does not appear that the presence of any bioactive agent in the claimed xerogel would affect the basic and novel characteristics thereof. In addition, the burden is on applicants to establish what is excluded by this language.

6. Claims 19, 20, 22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. '339 in view of Ahola et al. '802.

In the alternative to the rejection above, the skilled artisan would have found the claims obvious over the teachings of Ahola et al. '339 taken in view of the teachings of Ahola et al. '802.

As noted above, '339 teaches a silica xerogel that meets that found in claim 19. This reference teaches using the xerogels for the controlled release of a bioactive agent but does not teach using the xerogel as a coating layer on a wound dressing.

As taught in Ahola et al. '802, column 1, lines 34 and on, the combination of biodegradable xerogels in a multilayered material makes it possible to alter the delivery properties by using different core materials. This teaches that applying silica sol gels as a coating to a "body" allows the skilled artisan to target drug delivery and location. Again see column 5, lines 35 to 38, which teach applying xerogels to a woven or non-woven mat for use as a temporary skin substitute or for guided tissue regeneration.

Thus one having ordinary skill in the art would have been motivated by the teachings in Ahola et al. '802 to use the xerogel in Ahola et al. '339 as a coating on, for instance, a woven or non-woven mat in an effort to direct or specify the drug delivery location. In this manner the coated wound dressing claimed would have been obvious.

Regarding the specific coating weight, the Examiner relies on the rationale noted supra in paragraph 5. She also relies upon the rationale of record for the limitation of claim 33.

7. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

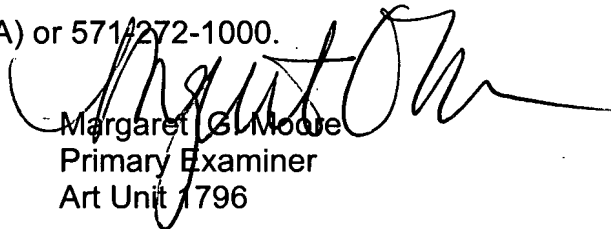
Art Unit: 1796

The prior art fails to teach or suggest a xerogel including an epoxysilane in addition to the hydrophobic organic silicon compound as claimed. Note that since the epoxysilane is effective to provide the anti-adhesive layer with partially hydrophilic properties, such a silane must be present in the anti-adhesive layer.

8. Biteau et al., Ahola et al. '518 and Koshinen et al. are cited as being of general interest. None of these references teach or adequately suggest the necessary combination of a wound dressing and a xerogel as claimed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Margaret G. Moore whose telephone number is 571-272-1090. The examiner can normally be reached on Monday and Wednesday to Friday, 10am to 4pm.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Margaret G. Moore
Primary Examiner
Art Unit 1796

mgm
10/31/07